Do Researchers Have a Legal Duty to Disclose Individual Research Findings to Research Subjects? Why They Might, and Why it Matters

Do Researchers Have a Legal Duty to Disclose Individual Research Findings to Research Subjects? Why They Might, and Why it Matters

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Abstract

Exploration of the frontiers of biomedical research requires the willing participation of millions of human subjects. This participation primarily facilitates breakthroughs in generalized knowledge, but it also reveals personal information about the human subjects, some of which is potentially significant. Researchers who possess such personal information about the subjects of their studies arguably have – or should have – a legal duty to inform the subjects, at least when the information is medically significant. While there is no such explicit duty in positive law and none has been previously announced by a common law court, some courts have softened the requirements for finding that a physicians and life insurers have such a duty in analogous situations. The law has thus developed such that a finding that researchers have a similar duty would appear to be a logical next step. In fact, the argument for a duty to disclose for researchers is arguably even stronger. Courts faced with litigation alleging a researcher duty to disclose should not, however, merely import the reasoning from the analogous cases because doing so would further cloud the already fuzzy state of the interaction between researchers and subjects. And a federal regulatory answer appears to be preferable than the imposition of a duty via the common law.

Introduction

Research with human subjects in all its varied forms is a large and growing enterprise. Tens of millions of individuals have already participated as subjects in one or more research protocols, and millions more participate each year.[1] Government and industry combined spend billions annually to support as many as twenty thousand research studies,[2] many of which are individually large and complex enterprises in their own right.[3] And these numbers are, if anything, likely to increase even further.[4] Besides the growth in research, two other trends related to research are apparent. First, research-related litigation is on the rise and appears likely to become even more widespread.[5] Sparked at least in part by recent widely publicized instances of harm befalling research subjects,[6] plaintiffs' attorneys are suing both more often and more creatively. Related to this is the second trend: public trust in research is declining and, as a result, at least some types of research are struggling to find adequate numbers of human subjects.[7] As a result of these trends, exposure to potential liability and public perception are both increasingly important.

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[1] *See* Richard S. Saver, *Medical Research and Intangible Harm*, 74 U. Cin. L. Rev. 941, 944 (2006).
[2] *Id*.
[3] To take just one recent example, researchers recently announced that three genetic studies that collectively involved approximately 28,000 subjects culminated in the identification of a gene linked to lung cancer. *See* Steven Reinberg, *Gene Variants Linked to Lung Cancer Identified,* Washington Post, April 2, 2008.
[4] Consider, for example, that the recent passage of a Congressional bill that will prevent discrimination based on genetic information should further increase the numbers of people willing to serve as subjects for genetic research. *See* Amy Harmon, *Congress Passes Bill to Bar Bias Based on Genes*, NY Times, May 2, 2008 (suggesting that the new law will spur increased participation in genetic research studies).
[5] Michelle M. Mello, David M. Studdert, & Troyen A. Brennan, *The Rise of Litigation in Human Subjects Research*, 139 Annals of Internal Medicine 40 (2003).
[6] The most notorious example of harm befalling a research subject is likely the sad case of Jessie Gelsinger, a young man whose participation in a clinical trial to test an innovative gene therapy in 1999 caused his death. For an example of one of the many media reports of the tragedy, *see* Sheryl Gay Stolberg, *The Biotech Death of Jesse Gelsinger*, N.Y. Times Mag., Nov. 28, 1999, at 136.
[7] Emily Anthes & Scott Allen, *US Cancer Researchers go Abroad for Trials*, Boston Globe, December 29, 2007, at A1.

Concomitant with all of this research is the discovery and generation of tremendous quantities of data specific to individual subjects, including – but not limited to – genetic information. Much of this data is irrelevant to subjects' interests because it lacks predictive value, has very uncertain meaning, or is otherwise uninformative. Some, however, is different – some of the personal data learned during the course of research with human subjects bears directly on individuals' health. Despite the fact that much individual data has already been generated and that both the quantity and the quality of data generated seem likely to increase, there is a lack of clear guidance for researchers regarding whether and when such information should be divulged to the subjects on whom it bears.

In this environment, the potential exists for litigation alleging that a researcher was negligent for failure to disclose to a subject an individual research finding of medical significance. Such litigation would, in all likelihood, be a case of first impression for a court and would raise a heretofore unanswered question: should a researcher have a legal duty to disclose medically significant individual research findings to a subject? A court faced with this question would appear to have precious little legal authority to which to turn for guidance. And although it may seem a reach to suggest that a court would find that researchers have such a duty, the primary argument against a duty – that researchers are not acting for the benefit of their subjects – has been weakened in other contexts. Therefore, given the right set of facts, a court may be actually be rather amenable to extending the duty to disclose to researchers. It would be a mistake, however, to import wholesale the reasoning from analogous cases, because doing would demonstrate a lack

of sensitivity to context and would threaten to further blur subjects' already fuzzy understanding of clinical research.

My first argument is a descriptive one: courts in several states have, by rejecting the traditional rule of no duty in the context of third-party physical examinations, opened the door to finding a similar duty for researchers and, in fact, the argument for such duty in the context of research is even stronger than in the context of third-party examinations. Second, while not necessarily disagreeing with the outcome of these cases, I argue that the specific analysis employed by many of these courts makes little sense and should not be lifted wholesale into the research context. Finally, I examine the implications for research should a legal duty to disclose be found and provide a suggestion as to how best to proceed. Although I agree with the bulk of the literature that asserts that researchers have a moral duty to disclose medically useful results, I remain agnostic on the question of whether there ought to be a corresponding legal duty – the point here is that the primary arguments against a legal duty have been weakened considerably in other contexts and that, given the state of the common law, imposing a duty on researchers to disclose medically significant individual research findings is a logical next step.

The focus here is primarily on only one element of tort liability – duty. Of course, duty alone is insufficient to establish liability for negligence. The other three elements of negligence – breach, causation, and harm – must also be present. And it is far from certain that these other elements would be present in a researcher disclosure case. Accordingly, the remaining elements of negligence liability are also discussed briefly. [8]

[8] Two points need to be made at the outset. First, the vast majority of information learned about individual subjects during the course of research is probably unlikely to have present medical value to the subject and, accordingly, even if a duty to disclose did exist, most individual research findings would not trigger that duty. Ultimately, this is a question of the scope of the duty, not whether a duty exists at all, and it is

Part I of this Paper introduces the field of research with human subjects and briefly examines some of the potentially salient differences among types of research. Part II surveys the existing legal constraints on such research and explores other sources of guidance. In Part III, I argue that court decisions in the context of employment-related and life insurance physical examinations have opened the door to a researcher duty to disclose individual research findings, and I consider how such decisions might apply to researcher-subject relationships. Part IV discusses other elements of negligence liability in the research context. Part V explores some of the implications of a researcher duty to disclose, and the Paper concludes in Part VI.

I. Human Subjects Research

"Research with human subjects" is a broad term that encompasses a wide variety of research. It can be conceptualized in two broad categories: therapeutic research, which includes most clinical trials, can be distinguished from so-called "nontherapeutic" research in that the former has a possibility of immediate benefit to the subjects, whereas the latter has no such potential.[9] Within each category, the level of intervention, contact,

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discussed *infra* in Part IV.A. Second, I do not doubt that researchers will generally report medically significant information to their subjects. To the extent that this paper advances the arguments for a duty to disclose, it is not motivated by a distrust of researchers, and the intention here is not to suggest that they would intentionally seek to withhold from their subjects information that might be valuable to the latter.

[9] "Nontherapeutic" is but one possible term to describe research that does not offer the potential of immediate clinical benefit to subjects, but since this term has been used by courts, *see Grimes v. Kennedy Krieger Inst*., 782 A.2d 807, 837-38 (Md. 2001), I will use it here. The key distinction is that subjects who enroll in such research do not stand to benefit directly by their participation; thus, the obligations to such subjects arguably ought to be analyzed differently, as the *Grimes* court suggested. *Id.* To say that the analysis ought to be different is not to suggest that obligations to subjects in nontherapeutic research ought to be categorically more or less extensive. Clinical research often involves significantly more time and sacrifice on the part of the subjects, but subjects also sometimes receive potentially life-saving therapies as a result of their involvement. In short, the variety of research protocols in both the therapeutic and nontherapeutic settings prevents wholesale generalizations about differential obligations to subjects based on the type of research in which they are participating.

and time investment on the part of the subjects[10] varies considerably. At one end of this continuum are research projects such as population-based genetic epidemiology studies wherein subjects merely submit a tissue sample for analysis – blood or saliva, for example – and have minimal contact with researchers. At the other end are studies that are much more intrusive and time-consuming and in which subjects have much more contact with the researchers, who are themselves often physicians and, not uncommonly, are also the subjects' treating physicians (i.e. they have a preexisting physician-patient relationship with subjects). Many clinical trials fall into this latter category. Thus, the relationship between a subject and a researcher can be quite different depending on the particular protocol, and this difference in relationships is relevant to the duties that the researcher owes – or should owe – his subjects.

A. Individual Research Findings

Results obtained from research can come in a variety of forms, but "individual research findings" is herein taken to mean data specific to an individual that is learned as a result of that individual's participation in a research study, together with any information signifying the importance of that particular data, such as information that the data indicates the presence of a particular disease or condition or that it confers a susceptibility to a certain disease or chemical or to an adverse reaction to a certain medication. Such data might be generated during the course of clinical trials of a new drug conducted to gather data on safety and efficacy in hopes of garnering approval from

[10] Commentators debate over the best term to use in describing people who participate in research – "subjects" or "participants." I use "subjects" in this paper only because it is more common in the literature, but my usage of that term is not an endorsement of that term nor an indication that I find it preferable to "participant."

the Food and Drug Administration to market the drug,[11] or it could result from pre-clinical research.

An individual research finding, as conceived here, includes both data that are the intended goal of the research and data that are purely incidental findings. Data that are the goal of the research could include, for example, a genetic epidemiology study that finds that individuals with a certain allele of a given gene are at higher risk for contracting a given disease or diseases either by virtue of the genetic variation alone or in combination with certain environmental exposures (e.g. cigarette smoke). Or pharmacogenetic investigators may learn that those with a certain genotype are more likely to suffer adverse medical events when using a given medication. But although the data might be the goal of the research, it might be also be wholly incidental. A researcher might discover, for example, that a blood sample submitted for an unrelated study is HIV-positive. Or a brain imaging study might reveal the presence of an abnormal mass in the cerebrum. For the purposes of this discussion, however, whether a finding was intended or merely incidental to the research is unimportant. What matters for the present purposes is simply whether a researcher makes an individual research finding.

Like research, "individual research findings" is also a broad category, and it includes within it data that vary widely in their potential value to a particular subject. Data will vary regarding their predictive value, with a range from highly predictive of health outcomes to negligibly so. Similarly, data will also vary in their usefulness to a subject, and although usefulness is related to predictive value, it is not coextensive, because the extent to which there is a treatment or preventive action available for the

[11] For an overview of the new drug approval process, *see* Center for Drug Evaluation and Research, *Drug Approval Application Process*, available at http://www.fda.gov/cder/regulatory/applications/default.htm (last accessed May 15, 2008).

condition or disease is an independent variable. Thus, results might be both highly predictive and have relatively little usefulness if, for example, they indicate a significantly higher risk for a disease for which there is no prevention or cure.[12] The specific focus here is primarily on individual findings that are medically useful in the sense that there is some action that can be taken to prevent or ameliorate the condition indicated by the finding. Such results are said to have 'clinical utility': they have actual medical benefit for the subject.[13] Results with clinical utility are the focus of this analysis because a failure to disclose such results has the potential to cause harm to a subject by precluding his opportunity to take action to prevent or ameliorate a condition. On the other hand, a result with no clinical utility is seen as lacking in tangible benefit to the subject, so a failure to disclose such a result would seem highly unlikely to lead to a tangible harm. In other words, a duty to disclose might exist, and yet many research findings would fall outside the scope of that duty, so a failure to disclose such findings would not constitute a breach of the duty.[14]

There is a plausible argument, however, that the concept of clinical utility is too narrow a metric to accurately capture the full potential value of a research finding. For example, persons might find value in learning that they have a gene that puts them at increased risk for contracting a disease even when such disease is not preventable. This might be so because a person so informed could use the information to inform her future planning, both generally and for reproductive decision-making. She might also seek out

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[12] *See, e.g.*, Melissa Austin, *Ethical Issues in Human Genome Epidemiology: A Case Study Based on the Japanese American Family Study in Seattle, Washington*, 155 Am. J. Epidemiology 585 (2002) (explaining the study team's decision not to notify subjects who had an allele that was discovered to predispose for Alzheimer's disease on the basis that, because Alzheimer's disease is not preventable, the information would be of little value to the affected subjects).

[13] *See* Wylie Burke & Ron Zimmerman, *Ensuring the Appropriate Use of Genetic Tests*, 5 Nature Reviews Genetics 955 (2004) (defining "clinical utility").

[14] This point is elaborated further *infra* in Part IV.

others so afflicted for support. And she would plausibly be more motivated to actively seek out or monitor information related to the disease such that, should future research determine that certain behaviors or medications reduce the risk of contracting the disease, she will be better positioned to take advantage of the new information. For these reasons and others, the notion that clinical utility should define a threshold for reporting individual research findings has been increasingly criticized of late.[15] While important, this issue is ultimately a question of the scope of any duty to disclose rather than whether a duty should exist in the first place. Accordingly, a fuller discussion is presented below in Part IV, following the analysis of the duty.

The present focus on results with clinically utility is not an endorsement of that as the normatively desirable threshold. Rather, it is a pragmatic choice reflecting the nature of the legal inquiry. Although the question of whether any particular result should be disclosed (where 'should' has a legal rather than moral connotation) is ultimately a question of the scope of the duty, rather than whether a duty exists in the first place, a research finding lacking in clinical utility would present a weak factual case for a court to find a researcher duty.[16] Thus, for simplicity and clarity, this discussion assumes an individual research finding with significant clinical utility – i.e. information that would, if

[15] *See*, *e.g.*, Vardit Ravitsky & Benjamin S. Woolford, *Disclosing Individual Genetic Results to Research Participants*, 6 Am. J. Bioethics 8 (2006).

[16] Consider that in the cases discussed below in which courts held, for the first time, a duty to disclose in the context of third-party physical examinations, the information discovered by the examining party was typically very high in clinical utility – the presence of the HIV virus in the blood or an abnormality in the chest indicating the presence of lung cancer. In each case, the disease at issue was one that, with timely detection, could be treated, or whose progression could at least be slowed. Therefore, the failure to disclose the information to the examinee deprived him of a meaningful chance to prevent serious clinical harm or death. *See* cases discussed infra in Part III. Of course, a court does not actually *need* such a factual scenario to find a duty – it might find a duty, generally, but decline to find that the duty attached in the particular case at hand – i.e. that on the present facts, the failure to disclose was not a breach of the duty, perhaps because the information had no or little clinical utility. The point is that, although the degree of clinical utility is technically only at issue in determining the scope of the duty, it simplifies and clarifies the issue to assume a clinically useful result in this discussion. This should not, however, be taken as an argument that any duty to disclose should always be limited to clinically useful findings.

known to the subject, empower her with knowledge that she could act on to prevent serious injury or death, or at least to substantially increase her odds of doing so.

B. **Genetic Data**

Much of the literature regarding the disclosure of individual research findings focuses on genetic research because the distinctive properties of genetic information present the potential for unique benefits and risks to those with whom it is shared and thus present particular challenges germane to the decision whether to disclose.[17]

Genetic information is at once both highly personal and shared with family members; this familial nature of genetic information means that it can be valuable to people beyond merely the research subject, and the predictive nature of the information gives it potential usefulness for future planning and reproductive decision-making.[18] But those same properties also give rise to concerns about psychosocial harms, such as familial strife and increased anxiety about the individual's own future or possible effects on children.[19] There are also concerns that information about genetic susceptibilities could lead to stigmatization and discrimination in obtaining insurance or employment if such information is shared or becomes part of an individual's medical records.[20] Any determination whether to disclose genetic information should therefore consider these potential harms and attempt to balance them with any anticipated benefits that may

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[17] *See*, *e.g.*, National Bioethics Advisory Commission, *Research Involving Human Biological Materials: Ethical Issues and Policy Guidance*, at 71 (1999), available at http://bioethics.georgetown.edu/nbac/hbm.pdf (last accessed May 15, 2008) (hereinafter "NBAC").
[18] United States Department of Health and Human Services, Office for Protection from Research Risks, *Protecting Human Research Subjects: Institutional Review Board Guidebook*, at Chapter V, Section H (1993), available at http://www.hhs.gov/ohrp/irb/irb_chapter5ii.htm#h12 (hereinafter "IRB Guidebook").
[19] *Id*.
[20] *Id*.

accrue to the subject from learning genetic information.[21] This is made more difficult by the somewhat speculative nature of both the benefits and psychosocial harms, and since much genetic data learned during the course of research is preliminary in nature, the additional possibility of harm from providing information that proves ultimately inaccurate must also be taken into consideration.[22] In short, the calculation of harm and benefit from genetic information is far from straightforward. And because genetic information is seen as weightier and harder to understand, disclosure without accompanying genetic counseling is widely considered ethically problematic.[23]

The complicated calculus of the value of any particular bit of genetic information is, also, however, ultimately part of the inquiry into the scope of the duty, and it is discussed further *infra* in Part IV.

II. The Legal Landscape and Other Sources of Guidance

Most research with human subjects in the United States is subject to several layers of regulation. Federal regulations set a floor of protections for human subjects, one that can be added to by state law from the legislature or the judiciary. None of these sources of law, however, appears to directly address the question whether a researcher owes a legal duty to his subjects to disclose individual research findings. Federal regulations address disclosure in the context of research, but the concern is primarily with harms that may occur *during* the research, as a result of taking part in it, rather than from a failure to

[21] *Id*.
[22] *Id*.
[23] *Id.* ("Any disclosure of genetic information should be accompanied by appropriate counseling by trained genetic counselors.").

notify subjects of results that may indicate a susceptibility to a disease or adverse medical event. The common law also has little guidance to offer on this topic.

A. The Common Rule

Research with human subjects that (1) is supported by funding from the federal government or (2) takes place at an institution that is federally funded or (3) has as its purpose the support of an application to the Food and Drug Administration (FDA) is subject to federal regulation and oversight.[24] The practical effect of this is that nearly all research with human subjects in the United States is covered by the federal regulations known as the Common Rule.[25] Among other things, the Common Rule details the requirements for the informed consent process and establishes the system of protocol review by an Institutional Review Board (IRB). Each covered institution must have at least one IRB, and before a covered researcher can work with human subjects he must gain approval for his protocol from an IRB, which functions as an (ideally) independent body charged with safeguarding the rights and welfare of human subjects by ensuring that the research meets federal standards.[26] The Common Rule requires that the IRB evaluate whether the risks to subjects of the research are justified by its potential benefits and that potential subjects be fully informed about the nature, scope, and risks of the research.[27]

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[24] *See* Henry Greely, *The Control of Genetic Research: Involving the "Groups Between"*, 33 Hous. L. Rev. 1397, 1399 (1997).
[25] Barry Furrow et al., *Health Law* 980 (2d ed., 2000). The Common Rule has been adopted by numerous agencies, including the Department of Health and Human Services (DHHS) (45 C.F.R. 46), and the FDA (21 C.F.R. 50 and 56). Although there are slight differences between the DHHS and the FDA versions of the Common Rule, none of those differences appear to be salient for this topic. Accordingly, those differences will not be noted here, and for simplicity, the DHHS version will be cited throughout.
[26] Greeley, *supra* note24, at 1399-1400.
[27] *Id*. at 1400-1401.

The Common Rule does not, however, directly address the provision of results to subjects, in general. Section 46.116 of the Common Rule specifically addresses informed consent, and it states what must be disclosed to subjects as part of the consent process, including the purpose of the investigation and the potential risks and benefits from participation in the study.[28] A researcher's plan with regards to sharing (or not sharing) results is not one of the items that must be disclosed; hence, the Common Rule does not compel the inclusion of such information in the consent form. In fact, the only language in the Common Rule that addresses research *results* states that those that may indicate whether continued participation in the study is harmful must be revealed to subjects.[29] Thus, federal regulatory law is clear that results indicating a risk from remaining in the study should be communicated to subjects, but it does not address whether results that might be clinically significant but would not affect willingness to continue in the research need to be disclosed.

There are many examples of individual research findings – intended or incidental – that might affect a subject's willingness to continue in a study. For example, researchers who study couples where only one partner is infected with a sexually transmitted disease might discover that disease in the partner who was previously negative. Such a finding would be very germane to the couple's willingness to continue in the study. Accordingly, the Common Rule would appear to compel such a disclosure. But many other research findings would not be so directly related to continued

[28] 45 C.F.R. § 46.116.

[29] § 46.116(b)(5) ("(b) additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject . . . (5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.").

participation in the study and would not, as a result, come within the scope of the Common Rule's mandate to disclose. And those are the focus here.

Notably, the Common Rule prohibits any exculpatory language in the informed consent document that purports to release an investigator of liability: "No informed consent . . . may include any exculpatory language through which the subject or representative is made to waive . . . any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability or negligence."[30] Therefore, a researcher is not absolved of liability merely by meeting the requirements of informed consent.[31] This provision may become particularly relevant should researchers increasingly seek to contract around a general duty to disclose.[32]

B. HIPAA

Regulations promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA) may give subjects a right to access their individual research results under certain limited circumstances – if the information is kept in a "designated record set" by a "covered entity."[33] Research involving clinical care, such as

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[30] § 46.116.
[31] *See* Larry Palmer, *Reuschlein Lecture: Disease Management and Liability in the Human Genome Era*, 47 Vill. L. Rev. 1 (2002).
[32] See discussion *infra* Part V.A.
[33] United States Department of Health and Human Services, *Clinical Research and the HIPAA Privacy Rule*, at 1, 15 (2004), available at http://privacyruleandresearch.nih.gov/pdf/clin_research.pdf (last accessed May 15, 2008) ("Covered entities are health plans, health care clearinghouses, and health care providers that transmit health information electronically in connection with certain defined HIPAA transactions, such as claims or eligibility inquiries. Researchers are not themselves covered entities, unless they are also health care providers and engage in any of the covered electronic transactions. If, however, researchers are employees or other workforce members of a covered entity (e.g., a hospital or health insurer), they may have to comply with that entity's HIPAA privacy policies and procedures. Researchers who are not themselves covered entities, or who are not workforce members of covered entities, may be indirectly affected by the Privacy Rule if covered entities supply their data. . . .A designated record set includes any record that is maintained by the covered entity or its business associate that is a medical, billing, enrollment, or payment record or other record that is used to make decisions about the subject of the

clinical trials, are more likely to meet these criteria, so subjects enrolled in clinical trials are more likely to have a right of access to their individual findings. The actual number of research studies that would meet either condition is unclear; although it is likely that most would not – especially among those that do not involve clinical care – this remains an unresolved issue.[34]

Consent forms might seek to circumvent HIPAA requirements by explicitly stating that the results from the research will not become part of the subject's medical records. If results are not in the medical records, they will not be part of a 'designated record set'; in those circumstances, HIPAA would appear to be inapplicable. Even if results are entered into subjects' medical records and thus become part of a 'designated record set,' the right conferred by HIPAA is, at least explicitly, only a right of access – individuals have the right to inspect and obtain a copy of their health care information – and it thus apparently requires only that the results be given upon request, not that subjects be informed of results as a matter of practice. Moreover, because HIPAA does not create a private cause of action,[35] even if the researchers did violate these regulations, there would be no recourse for subjects in the courts (at least not in the federal courts).

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information. It may be, in some cases, that research data would not be considered part of the designated record set if, for example, the research data is not used to make decisions about the individual and not part of the medical record. In that case, the individual would not have a right to access the data, but this should be examined on a case-by-case basis with institutional officials.").

[34] United States Department of Health and Human Services, *Response of the Department of Health and Human Services to NBAC's Report Research Involving Human Biological Materials: Ethical Issues and Policy Guidance*, at 23 (2001), available at http://aspe.hhs.gov/sp/hbm/hbm.pdf (last accessed May 15, 2008) ([referring to HIPAA] "…its applicability to research in which health care is not provided (e.g., studies based solely on tissue samples with no clinical care component) is not entirely clear . . .") (hereinafter "DHHS Response").

[35] *Acara v. Banks*, 470 F.3d 569, 572 (5th Cir. 2006).

C. Case Law

Few published cases have addressed biomedical research at all, and only one published opinion appears to have addressed the issue of a failure to disclose results. The court in that case did not, however, ultimately reach the issue of whether a researcher has a duty to disclose individual research findings. Nonetheless, the decision is informative on several points.

In *Ande v. Rock*,[36] the Court of Appeals of Wisconsin rejected claims related to a lack of disclosure of an individual research finding indicating that the plaintiffs' child had cystic fibrosis (CF). The litigation resulted from a research study intended to test whether early nutritional intervention would improve outcomes for children afflicted with CF. The research design required a control group; therefore, only the parents of one-half of the children who tested positive for CF were notified, and only those children were afforded the early intervention.[37] The Andes' daughter was randomly selected to be in the control group.[38] Accordingly, although she was tested for CF when she was born, and although the test indicated that she had CF, the Andes were not notified of the test result.[39] By the time their daughter was diagnosed with CF, almost two years later, the

[36] 647 N.W. 2d 265 (Wis. Ct. App. 2002).
[37] *Id*. at 269. This case thus introduces an additional potential wrinkle into the analysis of whether researchers should have a duty to disclose: some protocols, such as the one at issue in this case, will *require* that subjects not be told if they have a medical condition. Full analysis of the implications of such protocols on any legal duty to disclose is beyond the scope of this paper, but it should be noted that, to the extent that a requirement that results not be reported is key to the research project, it may well tip any inquiry based on the totality of the circumstances against a duty to disclose in those particular circumstances. In any event, the assumption here is that research *requiring* non-disclosure of a medically significant individual research finding is the rare exception.
[38] *Id*. at 270.
[39] *Id*. Indeed, the research team maintained that they also did not know that the Andes' daughter had tested positive for CF because newborns were randomized into control and experimental groups prior to testing and thus only the test results from the experimental group were actually viewed by any researchers. In other words, although all children in the control group were tested, those test results were allegedly not

Andes had already conceived their second child, and that child was also afflicted with CF.[40] The Andes sued, alleging, among other things, that they should have been informed that their first child had CF because doing so would have allowed them both to treat her earlier and to avoid conceiving another child with CF.[41] In their complaint, the Andes alleged both medical malpractice and general negligence.[42]

The Wisconsin Court of Appeals upheld the trial court's dismissal of both the medical malpractice and the general negligence claims. On the former issue, the court stated that there was no physician-patient relationship necessary for medical malpractice. And the court found that the negligence claim, which was based on the theory that researchers have a duty to disclose individual research findings, was time-barred.

Thus, the *Ande* court decision is not particularly illuminating. But the case is still informative, for at least two reasons. First, it serves as an indication that research subjects who do not receive notification of individual research findings will, in some instances, feel so aggrieved that they will litigate, and they might well pursue claim based on a theory of a researcher-based duty to disclose. Second, it perhaps hints that courts might be reluctant to extend medical malpractice claims into the research context, at least in the context of a duty of disclosure. Because the relationship between the plaintiffs and the physicians in this case was so attenuated, however – it appears that there was no relationship whatsoever between them[43] – the *Ande* court's decision regarding the

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reviewed by any member of the research team until four years after the birth of the children. *Id*. An analysis of this 'willful blindness' defense might have proved useful in light of the potential increase in anonymization of research samples in response to a duty to disclose, *see* discussion infra in section V.B, but because the court found that the negligence claims against the researchers were time-barred, it did not explore this issue. *Id*. at 270 & n.4.

[40] *Id*. at 270.

[41] *Id*.

[42] *Id*. They also alleged deprivation of liberty and property interests as well as violations of due process.

[43] *Id*. at 272.

medical malpractice claim might be primarily the result of the particular facts of the case and, accordingly, its significance should not be overstated.

There is some case law that addresses researcher duty, generally, and, it purports to establish several important propositions. Most notably, the highest court in Maryland held, in *Grimes v Kennedy Krieger Institute*,[44] that there usually is a legal duty of care in nontherapeutic research[45] and that a breach of this duty can give rise to a viable negligence action. According to the court, this duty results from both the special nature of the relationship between the researcher and subject and from the contractual nature of the informed consent document.[46] Although the court did not specify exactly what this duty entails nor the precise conditions under which it arises, it noted that the duty will normally exist in nontherapeutic research, that it cannot be extinguished by the consent of the subject or IRB approval, and that whether it exists in a particular study is to be determined on a case-by-case basis.[47] The court also stated that the principal element of duty is foreseeability.[48] Thus, under *Grimes*, if the harm is foreseeable, there is likely a duty of care to help prevent the harm.

There is a key difference between the *Grimes* case and the issue at present, however. In the former, the researchers allegedly placed children in harmful situations (homes that had received partial lead-abatement but retained allegedly dangerous levels of lead) and kept them there despite knowledge of increased risk of harm (evidence revealed during the study of increased blood lead levels in children). Thus, the research

[44] 782 A.2d 807 (Md. 2001).
[45] Nontherapeutic research is said to be distinct from clinical or therapeutic research in that it does not offer any possibility of benefit to the research subject. The *Grimes* court noted that, because of this lack of benefit to the subject, the protections afforded subjects in nontherapeutic research should be, if anything, greater. 782 A.2d at 837-38.
[46] *Id.* at 858.
[47] *Id*.
[48] *Id*.

itself was alleged to have harmed the subjects, and the court found that the informed consent provided was inadequate. In contrast, when the issue is the disclosure of individual research findings, the research itself would not be directly harming the subjects. Whether the duty of care described by the *Grimes* court would extend to include warning a subject of a potential harm that had been uncovered by the research is not clear. But, at a minimum, *Grimes* establishes that researchers normally have a special relationship with their subjects and that they have duties to those subjects as a result. And such holdings could prove important in a future court's analysis of claim for a duty to disclose.[49]

D. Non-legal Guidance

The ethical foundation for the treatment of human subjects in research in this country comes primarily from three seminal documents: the Nuremberg Code,[50] the Declaration of Helsinki,[51] and the Belmont Report.[52] These documents are an obvious place to look for guidance on this issue, and some of the courts that have been faced with litigation arising from research have looked to them in the past.[53] But none of these three explicitly address whether researchers have an ethical obligation to disclose individual results to subjects. Nonetheless, the principles contained in these documents do inform

[49] Note, however, that *Grimes* is binding precedent only in Maryland. It is also apparently the only decision to date that has specifically held that researchers owe subjects a duty of care based on a special relationship. *See* Roger L. Jansson, *Researcher Liability for Negligence in Human Subject Research: Informed Consent and Researcher Malpractice Actions*, 78 Wash. L. Rev. 229, 255 (2003). Thus, the 49 remaining states and the federal courts do not necessarily recognize a similar duty of care in nontherapeutic research, and it is therefore unclear whether a non-Maryland court would find that the researcher owed his subject any duty of care whatsoever under common law.

[50] Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10 (1949), available at http://ohsr.od.nih.gov/guidelines/nuremberg.html (last accessed May 15, 2008).

[51] Available at: http://www.wma.net/e/policy/b3.htm (last accessed May 15, 2008)..

[52] The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1979), available at http://ohsr.od.nih.gov/guidelines/belmont.html (last accessed May 15, 2008).

[53] *See*, *e.g.*, *Grimes*, 782 A.2d 807.

the ethical discussion regarding results disclosure. For example, the Nuremberg Code and the Belmont Report both place great importance on the principles of autonomy and respect for persons as the underlying reasons for the necessity of informed, voluntary participation in research, and this has been used as the basis for arguing that researchers should share research results with subjects more often.[54]

Commentators generally support the notion that there is a *moral* duty to disclose medically important information. Some base that duty primarily on the moral duty to rescue another in need,[55] while others focus on the professional identity of the researcher and the nature of his relationship with his subjects.[56] When the information is seen as potentially more harmful than helpful – as with some genetic information – there is more disagreement in the literature about whether the information should be disclosed. But in situations where the research finding would have significant clinical utility to the subject, there appears to be broad agreement, based in large part on the principle of respect for persons, that there is a moral obligation to disclose. But although a moral obligation might inform the legal debate, it does not equate to a legal duty.

III. **Third-Party Physical Examinations and the Eroding Requirement for a Formal Physician-Patient Relationship**

Because the law regarding research with human subjects is sparse, there are few clear guideposts. Accordingly, a court faced with deciding whether a researcher should have a duty to disclose individually significant research findings might well look to other

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[54] *See*, *e.g.*, Timothy Banks, *Misusing Informed Consent: A Critique of Limitations on Research Subjects' Access to Genetic Research Results*, 63 Sask. L. Rev. 539 (2000).
[55] *See, e.g.*, Henry S. Richardson & Leah Belsky, *The Ancillary-Care Responsibilities of Medical Researchers*, Hastings Center Report, Jan.-Feb. 2004, at 26.
[56] *See, e.g.*, Franklin G. Miller, et al., *Incidental Findings in Human Research: What do Investigators owe Research Participants?*, J.L. Med. & Ethics (forthcoming 2008).

analogous areas of the law. And in one such area, the breakdown of the traditional requirement for the formation of a formal physician-patient relationship as a prerequisite to a physician duty to disclose has been giving way to a more pragmatic approach that focuses on, among other things, the medical significance of the information and general policy considerations. These legal developments point to a similar legal duty for researchers.

A strong argument against imposing liability on researchers for a failure to disclose individual research findings is that a researcher has no duty to his subjects – beyond those described in the Common Rule – because his interaction with them is not for their benefit but rather for the advancement of generalized knowledge. Thus, because the researcher acts to further research rather than to benefit (directly) his subjects, his primary loyalty is the former, and his relationship with subjects is not fiduciary in character. And his duties to subjects are therefore circumscribed by federal regulations. But this argument has been weakened in other contexts.

The traditional approach to third-party medical examinations supported this argument. In third-party examinations, an employer or insurance company retains a doctor or other medical professional to examine a prospective (or current) employee or an applicant for insurance.[57] Because the doctor in such situations acts for the benefit of the employer or insurance company and not for the examinees, courts have traditionally found no physician-patient relationship between the doctor and examinee and, as a result, have found no duty to the examinee beyond exercising reasonable care in the course of

[57] The physician might also, of course, be hired by a different third party. But the case law has mostly addressed scenarios in which the third party is an employer or a life insurance company, suggesting that these are the most common scenarios.

the examination.[58] Accordingly, examinees that were not notified of information that was discovered during the course of the third-party examination had no cause of action against the silent physician, even when such information was very medically significant.

But the traditional formalistic approach to these cases is waning, and the alternative approach that is gathering increased support signals that courts may be more sympathetic to the notion that researchers have a duty of disclosure. The formalistic traditional rule has given way in many jurisdictions to a more pragmatic approach,[59] and the reasoning deployed by the courts in these jurisdictions appears amenable to application in the researcher-subject relationship. Therefore, by analogy, the door has been opened such that, given the right set of facts, courts in some states are positioned to extend liability to researchers who fail to disclose individually meaningful research findings. Many of these cases, however, exhibit a formalism of their own in their treatment of physicians, and such reasoning would be problematic if imported into the research context.

A. **The Traditional Rule**

The traditional rule requires a formal physician-patient relationship to establish a duty of care on the part of the physician. Such a relationship is dependent "upon the existence of a contract, express or implied, that the doctor will undertake to treat the

[58] *E.g.*, *Murphy v. Blum*, 160 A.D.2d 914, 554 N.Y.S.2d 640 (App. Div. 1990); *Payne v. Sherrer*, 217 Ga. App. 761, 458 S.E.2d 916 (Ct. App. 1995). *See also Stanley v. McCarver*, 208 Ariz. 219, 221 92 P.3d 849 (2004) ("the traditional rule has been . . . that a formal doctor-patient relationship was necessary before tort liability could be imposed").

[59] *See Stanley*, 208 Ariz. at 221 ("The requirement of a formalized relationship between the parties has been quietly eroding in several jurisdictions.").

patient or at least engage in diagnosis as a prelude to treatment[,]"[60] and requires that the purpose of the interaction is, ultimately, to benefit the patient.[61]

Without the formalized relationship and its corresponding duty, the traditional rule views the physician as having no obligation to act to prevent harm to an individual. This stems from tort law's traditional unwillingness to impose a general legal duty to rescue on individuals absent some particular relationship between parties imposing such a duty.[62] Thus, for example, a pedestrian who sees that a nearby blind man is about to step in front of a car has no legal duty to prevent the impending accident, even though it might require but little effort on his part,[63]and, in the absence of duty, the pedestrian is not liable for negligence for failing to intervene to help the blind man. Similarly, unless a physician has entered into the formal relationship with another party that establishes the latter as his patient, he has no legal duty to help or rescue that party, even if the physician possesses potentially life-saving information that could be disclosed with minimal burden.

Examples of the application of the traditional rule include terse opinions quickly concluding that no physician-patient relationship exists when the doctor has "neither offered nor intended to treat, care for, or otherwise benefit the individual[,]"[64] and that no duty to treat or examine attaches when the physician was not engaged to "treat or advise" the examinee.[65]

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[60] *Green v. Walker*, 910 F.2d 291, 293 (5th Cir. 1990).
[61] *See*, *e.g*., *Thomas v. Kenton*, 425 So.2d 399 (La.App. 1982) (finding no physician-patient relationship because "[t]he doctor was hired by the company for their benefit and any benefit that their employees receive from having a doctor there to conduct these examinations was only secondary in nature.").
[62] Rest. 2d Torts § 314 (1965).
[63] *Id*. at comment c.
[64] *Payne v. Sherrer*, 217 Ga. App. 761, 762 (Ga.App. 1995) (quoting *Peace v. Weisman*, 186 Ga.App. 697, 698 (Ga.App. 1988)
[65] *Murphy v. Blum*, 160 A.D.2d 914, 915 (N.Y.A.D. 2 Dept. 1990).

Therefore, under the traditional approach – which is still the law in many states – a physician hired by a third party to perform a physical examination has no duty to the examinee beyond performing the examination with care (i.e. not harming the examinee during the course of the examination). And thus, even if the doctor discovers very medically significant information about the examinee -- information that if conveyed to the examinee would allow the latter to act to prevent harm to himself -- he has no duty to convey it to the examinee. And absent a duty, an examinee who later learns that the doctor's inaction foreclosed an opportunity to prevent harm has no cause of action for negligence against the doctor. Application of the traditional rule to the research context would seem to foreclose a duty on the part of the researcher because he, too, is not acting primarily for the benefit of his subjects. Although the traditional rule would directly apply only to physician-researchers, if it is read more broadly, it can be taken to mean that an interaction with a professional is insufficient to give rise to a duty on the part of that professional when the point of that interaction is to benefit a third party. And that reading supports the notion that researchers have no duty to disclose individual research findings to their subjects.

B. **The Alternative Approach**

The traditional rule regarding third-party examinations is changing, however, and with it the implications for researchers' disclosure duties to their subjects. In a number of jurisdictions, courts have been unwilling to rigidly apply the formal requirements of a physician-patient relationship when faced with preventable harm.

The breakdown of the strict requirement for a physician-patient relationship has its roots in two different areas of jurisprudence which each have established a willingness to impose duties on professionals flowing to persons other than the party with whom the professional interacts – *Tarasoff* and other duty to warn cases, on the one hand, and wrongful life actions, on the other.

The seminal case establishing a duty to warn a third party is *Tarasoff v. Regents of California*, in which the California Supreme Court held that a psychotherapist who had formed a treatment relationship with an individual had a duty to warn a third party of the patient's stated intention to harm the third party, notwithstanding the lack of any relationship between the psychologist and the third party.[66] The most important element of that duty, the court determined, was the forseeability of the harm to the third party.[67] Other factors that the court noted were relevant to the duty inquiry included the burden on the defendant, the consequences to the community, and the moral blame of the defendant's conduct.[68]

The duty to warn established in *Tarasoff* was subsequently expanded upon in the context of a physician-patient relationship involving genetic diagnoses and potential harms to family members. In *Safer v. Pack*[69] and *Pate v. Threlkel*,[70] appellate courts in New Jersey and Florida, respectively, held that a doctor who treated a patient with a genetic condition had, under certain circumstances, a duty to the patient's relatives to inform them of the patient's condition and their corresponding risk. Although the courts differed on how such a duty should be discharged – the Florida court held that the duty

[66] 551 P.2d 334 (Cal. 1976).
[67] *Id*. at 342.
[68] *Id.*
[69] 677 A.2d 1188 (N.J. Super. Ct. App. Div. 1996)
[70] 661 So.2d 278 (Fla. 1995)

would be fulfilled merely by informing the patient of the potential familial implications,[71] while the New Jersey court stated that, in certain circumstances, there might be a duty to inform the patient's relative(s) directly[72] – they agreed that the lack of any physician-patient relationship (or any contact whatsoever) between the physician and the patient's family members was not dispositive and did not bar the finding of a duty running from the physician to his patient's relatives.

Wrongful life jurisprudence has also, in some circumstances, helped set the groundwork for courts to reject the requirement of a traditional physician-patient relationship. A wrongful life cause of action is one that is advanced on behalf of a child born with a disability against a physician who allegedly should have made the parents aware of their genetic status or the fetus's disabling condition prior to conception or birth so that the parents could have chosen to not reproduce, to use technology to select against afflicted embryos, or to abort the afflicted fetus. Essentially, a wrongful birth claim posits that the child would have been better off had he not been born. Partly for that reason, most jurisdictions have refused to recognize a wrongful life cause of action. But where wrongful life is recognized, it has helped establish the notion of a duty running to non-patient third parties. Relying in part on either duty to warn or wrongful life jurisprudence, a number of courts have rejected the traditional rule in the context of both employment-related and life insurance physicals.[73]

Many more courts have found a duty to disclose in the context of employment-related physicals than in pre-insurance examinations, in part because the former tend to be conducted by physicians whereas the latter do not. And the courts that reject the duty

[71] *Id*. at 282.
[72] *Safer*, 677 A.2d, at 1192-93.
[73] See discussion infra in Parts III.B.1 and III.B.2.

to disclose where physicians are absent apply similar reasoning to those courts that impose duties on physicians when they are present: they both rely in part on a limited view of physicians in a manner that is insensitive to context. And this mode of analysis would be problematic if applied to physician-researchers because it would ignore the different role played by a physician when she is a researcher and, in doing so, it would threaten to further blur the public's already fuzzy understanding of research, with potentially problematic results.

1. **Employment-related Physical Examinations by Physicians**[74]

Numerous courts have now held that that, despite the traditional rule, physicians conducting employment-related physical examinations of employees (prospective or current) at the behest of employers have a duty to reveal important medical information[75] discovered during the course of the examination to the examinee.

The depths of analysis in these cases have varied considerably, but the courts tend to echo similar themes. Two earlier cases relied heavily on the notion that examinees justifiably expect *physicians* to inform them of medically significant information regardless of whether the exam was for their own benefit. In *Green v. Walker*,[76] the Fifth Circuit Court of Appeals, applying Louisiana state law, relied in large part on the notion that when one places himself "in the hands of a person held out to the world as skilled in

[74] Most, but not all, of the cases in this category involve physical examinations conducted prior to and as a prerequisite to employment. But some involve physical examinations conducted after an individual has been working for an employer for a period of time, such as an annual exam.
[75] The precise description of the type of information that triggers such a duty varies from court to court, but each of the opinions deals with factual scenarios involving medical information that portends consequences that are both serious and preventable – at least to some extent – given knowledge of the information.
[76] 910 F.2d 291 (5th Cir. 1990).

a medical profession"[77] he has a reasonable and justifiable expectation that the physician will notify him of "any incidental dangers that he discovers of which he is cognizant due to his peculiar knowledge of his specialization."[78] And in *Daly v. United States*, a panel of the Ninth Circuit Court of Appeals, applying Washington state law, held that physicians had a duty to notify examinees of "abnormal findings" discovered during the examination.[79] In reaching this conclusion, the court relied in part on *Green's* reasoning regarding societal expectations of physicians.[80] More recently, state supreme courts in New Jersey and Arizona were particularly thorough in their respective analyses of the duty, but while both included other bases of support for finding a duty, both also relied in part on their perceptions of examinees' expectations of physicians as healers.

In *Reed v. Bojarski*, the New Jersey Supreme Court held that a physician who conducts a third-party physical examination has a non-delegable duty to disclose significant medical findings to the examinee.[81] This duty, the court found, stemmed primarily from public policy considerations and expectations of physicians, which in turn was shaped in part by the "evaluative purpose" of the exam.[82] Ultimately, the court said, "whether a duty exists is . . . a question of fairness" involving "a weighing of the relationship of the parties, the nature of the risk, and the public interest in the proposed solution."[83] While the relationship between the parties is important, the court said, its exact nature is "simply a factor to be considered in determining what duty exists."[84] But

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[77] *Id*. at 295-96
[78] *Id*. at 296 (quoting *American Mfr. Mut. Ins. Co. v. United Gas Corp*., 159 So.2d 592, 595 (La. App. 1964).
[79] 946 F.2d 1467, 1470 (9th Cir. 1991) (applying Washington state law).
[80] *Id*. at 1470-71,
[81] 166 N.J. 89 (2001).
[82] *Id*. at 109
[83] *Id*. at 106.
[84] *Id*.

by focusing on society's expectations of physicians, the court may have limited its holding to relationships involving medical doctors.

The Arizona Supreme Court arguably extended the duty to disclose one step further by imposing a duty on a radiologist who apparently had no direct contact with the examinee. In *Stanley v. McCarver*, the court held that a radiologist who examined x-rays of an employee's chest had a duty to notify the employee of an abnormality that indicated a potentially life-threatening condition – lung cancer.[85] In reaching its decision, the *Stanley* court noted several things of potential relevance to the researcher-subject relationship. First, the court rejected the defendant's argument that imposing a duty would open the floodgates to litigation and would thereby chill physicians from performing pre-employment physicals.[86] In a related point, the court suggested that physicians could deal with this issue via contract, by, for example, requiring as a condition of performing the examination that examinees consent to having the results reported only to the employer.[87] Also, to allay concerns about a general duty to rescue, the court stated that it was not imposing a duty solely because a physician is in a position to prevent future harm. Instead, the court found that the duty "emanates from the panoply of social concerns that generally inform tort law"[88] and suggested that such concerns included an individual's expectations when he interacts with a physician, whether the party in possession of the information is in a unique position to prevent harm, and general considerations of public policy.[89]

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[85] 208 Ariz. 219 (2004).
[86] *Id*. at 225.
[87] *Id*. The court did not address whether, in that circumstance, the duty would flow to the employer.
[88] *Id*. at 226.
[89] *Id*. at 224-25.

Two themes emerge from the cases dealing with employment-related physicals. First, courts have tended to formalistically focus on the fact that the party possessing the information was a physician, and they have imputed expectations accordingly, without examining the particular, context-specific role of the physician at the time of the examination. None of the decisions discussed in this section undertook an in-depth discussion of the interaction between the doctor and examinee, nor did they indicate what the particular examinee's expectations actually were or whether he signed a consent form acknowledging that the doctor had no duty. Importantly, this focus on physicians arguably limits the duty to medical doctors. Second, courts tend to engage in broad inquiries when evaluating whether a duty should attach and thus consider a number of factors, including the burden on the physician to disclose the information, the seriousness of the information, whether the physician was in a unique position to prevent harm, and often ill-defined general policy or social concerns.

2. **Pre-Insurance Physicals**

Most of the court decisions that have addressed the duty to disclose in the context of pre-insurance physical examinations -- which typically do not involve physicians -- have indicated that the physician-based limits hinted at by the courts in the employment-related physicals cases will be taken seriously. These decisions, too, are hampered by a formalistic, narrow view of physicians, a view that would be problematic were it imported into the research context.

For example, a New Jersey appellate court decision after *Reed* indicated – but did not affirmatively state – that the key bases for the holding in *Reed* were the presence of a

physician and the examinee's corresponding expectations. In *Nolan v. First Colony Life Insurance Company*,[90] the court declined to extend *Reed* beyond the context of a physician in a pre-employment physical and thus refused to impose an analogous duty for a pre-insurance examination in part because no physician was involved. The facts in *Nolan*, however, varied in other potentially significant ways from those in *Reed*, such that it is not ultimately clear whether a lack of physician involvement in the former was the dispositive factor. For example, in *Nolan*, there were no significant "abnormalities" revealed in the blood test conducted for the insurance company – it revealed only slightly elevated liver enzyme levels.[91] Furthermore, the *Nolan* court noted that the "commercial setting" in which the pre-insurance testing took place precluded a trust or reliance similar to that in *Reed*.[92] Thus, *Nolan* interprets the holding in *Reed* to be based in no small part on the expectations that people have in physicians, but because the ultimate decision in *Nolan* rested on a combination of factors beyond the absence of a physician, it is not entirely clear what the court would have done had there been, for example, no physician in the mix but clearer evidence of a pressing medical problem, or, perhaps, a less "commercial" setting – like research.

Similar reasoning has produced similar results in other pre-insurance examination cases.[93] The Fifth Circuit Court of Appeals, in *Deramus v. Jackson Nat. Life Ins. Co*., drew a strong duty-related distinction between situations in which a physician was

[90] *Nolan v. First Colony Life Insurance Company*, 345 N.J. Super. 142, 784 A.2d 81 (N.J. Super. Ct. App. Div. 2001).
[91] *Id*. at 150.
[92] *Id*. at 150-51.
[93] Note that this issue is addressed in published opinions less often than might otherwise be expected because most states impose such a duty by statute. *See* Hannah Greenwald, *What You Don't Know Could Save Your Life: A Case for Federal Insurance Disclosure Legislation*, 102 Dick. L. Rev. 131, 132 (1997) (noting that at the time of writing, 29 states had such laws).

involved and those with no medical doctor.[94] Relying in part on the reasoning in *Deramus*, a federal district court in Ohio declined to impose a common law duty to notify an applicant that his blood had tested for positive for HIV on either the insurance company, because "the relationship between an insurance company and an applicant is commercial, not medical[,]" or the company that employed the paramedical who examined the plaintiff, in part because the examiner was not a physician.[95] And in *Petrosky v. Brasner*, a state appellate court in New York found no duty on an insurance company in part based on the conclusion that the fact that the plaintiff was not examined by a physician meant that he could not have forseeably been induced to forego necessary treatment[96] -- the implication being that, had a physician been present for the examination, the plaintiff would justifiably have had much different expectations.

There is thus a body of law from what I will refer to as the "physician-centered cases" that bases the duty to disclose individually significant medical information discovered during the course of a third-party medical examination at least partly on the status of the examiner – i.e. whether she is a physician. But this bit of formalism is also showing signs of giving way to a more pragmatic and context-sensitive approach, and this latter mode of analysis ultimately holds more promise for application in the research context.

The latter type of analysis is demonstrated in minority opinions in two of the cases that held no duty in the context of pre-insurance physicals. The concurring opinion

[94] 92 F.3d 274, 280 (5th Cir. 1996) (applying Mississippi law).
[95] *Eaton v. Continental General Ins. Co*., 147 F. Supp. 2d 829, 834, 839-40 (N.D. Ohio 2001).
[96] 279 A.D. 2d 75, 78 (N.Y.A.D. 1 Dept. 2001).

in *Nolan*[97]rejected the majority's conclusion that insurance companies have no duty to disclose abnormal findings and stressed that "tort duties arise from the qualities of a relationship not the status of the parties."[98] The *Nolan* concurrence also rejected the idea that a cause of action for an increased risk of harm should be limited to the medical malpractice context; instead, in the concurring judge's view, it should also apply to other types of special relationships.[99] Similarly, the dissenting judge in *Petrosky* flatly rejected the notion that the existence of a duty should turn on whether the examiner was a physician and noted the incentive problem that such a rule would create – limiting the duty to circumstances in which a physician was involved would encourage insurance companies and other third parties to employ non-physicians to conduct examinations and interpret the results.[100] This nascent development in the law – it is probably premature to identify it as a trend – has important implications for researchers because it suggests that at least some judges are willing to see beyond the physician-based limits of the cases involving employment-related physicals and extend the duty to disclose to other parties.

Similar logic convinced a majority in one court to impose a duty to disclose important medical information in the context of physical examinations conducted pursuant to an application for life insurance. In *Pehle v. Farm Bureau Life Insurance Company*,[101] a divided three judge panel[102] of the Tenth Circuit Court of Appeals held that, under Wyoming law, a life insurance company had a duty to notify an applicant

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[97] Judge Kestin concurred only because he agreed that the plaintiff had failed to demonstrate that the information that was not disclosed was not clearly significant enough that the disclosure would have prevented harm. 345 N.J. Super. at 155 (Kestin, J., concurring).
[98] *Id*. at 155-56.
[99] *Id*. at 157.
[100] 279 A.D.2d 75, 83 (Saxe, J., dissenting in part).
[101] 397 F.3d 897 (10th Cir. 2005).
[102] The dissenting judge argued that the question should have been certified to the Wyoming Supreme Court rather than answered directly by the federal court, which had jurisdiction based on diversity. *Id*. at 905-06 (Tacha, J., dissenting).

when a blood test conducted pursuant to his application for life insurance revealed that the applicant was HIV-positive.

Pehle can be seen as an important extension of the law towards researcher liability for at least two reasons. First, the court imposed a duty on an insurance company, rather than a physician. In doing so, the court discounted the importance of the traditional role of the party holding the information, a factor that loomed large in the analysis of the physician-centered cases. In its analysis, the Tenth Circuit panel stated that, "[w]e do not think that insurance companies must exist to treat or diagnose HIV in order for a duty to arise that necessitates that applicants be properly put on notice to inquire further."[103] Thus, *Pehle* arguably removes the physician-based barrier to duty left by *Reed* and *Stanley*. In the course of doing so, it also signaled the contours of a new limit by declining to impose a duty on the laboratory that tested the plaintiff's blood, finding the relationship between the applicant and the laboratory to be "so attenuated"; the insurer, by contrast, had a "good deal of contact" with plaintiff.[104]

Second, the *Pehle* court based its decision in large part upon a notion that duty could arise based on a relationship of "trust and confidence" and, importantly, found that the relationship between an insurer and a prospective insured had such a quality.[105] This latter aspect of the holding seems dubious, especially insofar as it relies on the tenuous claim that an insurer acts to benefit its customers. But to the extent that it implies that the possession of individual A's confidential information by party B is sufficient to create a

[103] *Id*. at 903.
[104] *Id*. at 901. Note that this apparent requirement for "contact" with the examinee stands in contrast to the *Stanley* court, which found that the duty applied to a radiologist who apparently had no contact with the examinee. 208 Ariz. 219.
[105] *Id*. at 903-04.

relationship of trust and confidence[106]-- or perhaps that such a relationship is created when A gives permission to B to test his blood and learn confidential information – *Pehle* suggests that researchers might too have such a duty. In fact, the argument for a duty to disclose based on the nature of the relationship would appear to be much stronger in the context of the researcher-subject interaction than it is for the association between prospective insured and insurer.[107]

Despite the problems with the assertion that the insured-prospective insurer relationship is one of trust and confidence, the *Pehle* court – and the judges in the minority in *Petrosky* and *Nolan* – arguably approach the issue of duty more sensibly, by refusing to narrowly focus on the traditional role of the examining party, because the traditional role inquiry should not be dispositive. The traditional role might well factor in to the ultimate question of expectations, of course, but one problem with the physician-centered opinions is that they fail to acknowledge that physicians may play different roles, and that our expectations of them should vary with those roles. Yes, physicians do hold themselves out to the world as healers, but that is not all that they do. Physicians sometimes act in other roles – as scientists, for example – and when they are wearing the scientist hat, their professional role is different and expectations should be adjusted accordingly.

This argument is not meant to suggest that the employment-related decisions were wrongly decided on the merits, however. There are legitimate justifications for imposing a duty on physicians in the context of employment-related physicals – and some of the decisions discussed above relied in part of such justifications. But tying that duty to the

[106] The court hints that this is the crux of the "trust and confidence" analysis, but it doesn't say that explicitly. *See id*.
[107] This point is developed further *infra* in Part III.D.

physician's professional role—as if she has only one function that is the same in all her endeavors – is problematic because it ignores context and potentially hampers physicians' ability to engage in other pursuits.

Research exacerbates the tension in the physician-centered decisions and further highlights the pitfalls of their approach. Applying traditional role-based rationales for duty in the research context would be particularly troubling, given the prevalence of physician-researchers and the difficulty that many research subjects already have understanding that the purpose of the research is not to help them directly but to advance general knowledge. This phenomenon, the therapeutic misconception,[108] is already widespread, and importing the reasoning from the physician-centered cases into the research context threatens to further exacerbate subjects' misunderstanding, which could in turn further erode public trust in research.[109]

So, in one sense, although *Pehle* arguably takes significant steps toward researcher liability, *physician-researchers* may ultimately find it to be a preferable frame through which to view researcher liability lawsuits, because by focusing on the actual role of the party with the information in the particular context of his interaction with the subject rather than narrowly deferring to the traditional role, the *Pehle* approach might actually provide more protection from liability, at least for those researchers who are also physicians. But at the same time, it threatens to open a new door to a duty to disclose on non-physician researchers, especially insofar as it sets forth an especially expansive view of relationships of trust and confidence.

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[108] *See* Paul S. Appelbaum et al., *False Hopes and Best Data: Consent to Research and the Therapeutic Misconception*, Hastings Center Rep., April, 1987, at 16.
[109] This point is discussed further *infra* in section III.D.

Of course, to say that *Pehle's* frame of looking at the issue is better is not an endorsement of *Pehle's* ultimate conclusion about the relationship between insured and insurers, which is both unconvincing and unsupported. Thus, to the extent that *Pehle* opens the door to a finding of a relationship of trust and confidence in many and varied interactions (and, of course, to the extent that the decision gains any traction – which does not yet appear to be the case) its reasoning has the potential to lead to the application of many more – perhaps too many more – duties to rescue.

C. **Application to researchers**

The rationale for a duty to disclose medically significant information in the context of third-party physical examinations applies with at least equal force in the context of a researcher-subject relationship. There are, of course, significant differences between the nature of the interaction between the examiner and examinee in third-party physicals and the general relationship between researchers and subjects. And, admittedly, not all of these differences point in the direction of a stronger argument for researcher duty. Furthermore, there are also very significant differences among research protocols regarding the level and type of researcher-subject interaction. In general, however, the case for researcher duty is potentially stronger than that for third-party examiner duty, for several reasons.

1. **Nature of the Relationship**

First, a researcher and subject have, by virtue of their interaction, entered into a relationship that already imposes duties on the researcher, such as those outlined in the

Common Rule. Imposing a duty to disclose individual research findings on researchers thus would not be akin to grafting a duty onto a relationship that previously had none. Rather, as in *Tarasoff*, *Safer*, and *Pate*, layering the duty on top of pre-existing relationship-based duties both makes more sense from an expectations-based viewpoint and is less troublesome because it inherently limits the duty to rescue.

Arguably, however, the researcher-subject relationship is not dissimilar from the relationship between examiner and examinee in the context of third-party physicals, because the latter, too, involves at least a minimal duty (to not harm the examinee during the course of the examination). But the researcher-subject relationship has an importantly different quality. For example, commentators disagree over whether a researcher is in a fiduciary relationship with his subjects. One argument that the relationship is fiduciary, at least when the investigator is also a physician, draws on the uncertain state of the term 'fiduciary' in the law and the vesting of discretionary powers by the subject in the physician-researcher.[110] And one court has hinted that it might consider the relationship to be fiduciary.[111] Others, however, posit that the relationship cannot be fiduciary because the researcher's primary loyalty is to his protocol rather than to any one subject.[112] A resolution of this disagreement is beyond the scope of this paper, but two points are important to note here. First, the existence of this academic dispute

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[110] Paul B. Miller and Charles Weijer, *Fiduciary Obligation in Clinical Research*, 34 J.L. Med. & Ethics 424, 428-32 (2006).

[111] *See Vodopest v. MacGregor,* 913 P.2d 779, 788 (Wash. 1996) ("Scholars on the subject of the ethics of medical research describe the relationship between investigator and subject as a fiduciary relationship."); *but see Greenberg v. Miami Children's Hospital Research Inst., Inc*., 264 F. Supp. 2d 1064, 1072 (S.D. Fl. 2003) ("There is no automatic fiduciary relationship that attaches when a researcher accepts medical donations and the acceptance of trust, the second constitutive element of finding a fiduciary duty, cannot be assumed once a donation is given.").

[112] *See*, *e.g*., E. Haavi Morreim, *Litigation in Clinical Research: Malpractice Doctrines Versus Research Realities*, 32 J.L. Med. & Ethics 474, 477-78 (2004) (arguing that researchers are not in a fiduciary relationship with their subjects).

suggests that the nature of the researcher-subject relationship is one that has at least some fiduciary qualities, and, accordingly, should have both heightened duties and expectations. Second, the relationship does not have to rise to the fiduciary level for duty to attach – it need only satisfy the lower bar of a special relationship. And while the disagreement about whether the researcher-subject relationship is fiduciary focuses primarily on situations in which the researcher is also a physician, the interaction between non-physician researchers and their subjects in nontherapeutic research has already been characterized by one court as just such a special relationship.[113] Thus, because the researcher-subject relationship is possibly fiduciary and probably "special," it is qualitatively different than the interaction between examiner and examinee in third-party physicals.

The second reason that the argument for a duty to disclose is stronger in the research context is that the fundamental nature of the relationship between researcher and subject is different because each party involved is not acting either solely for his own benefit or to protect another's financial interests. When a doctor examines a person for the benefit of a third party, he is acting for himself and for the third party, but not for the examinee. And the examinee submits to the examination for self-interested reasons – namely, so that he can obtain or keep a job. The interaction with a life insurance company is essentially an arms-length transaction in the marketplace. The insurance company acts for profit, and one seeking insurance acts to protect his family. The insurance company examines to protect its own interests: the results of the examination are used to inform the decision whether to offer life insurance and, if so, what rate to charge for it.

[113] *See Grimes*, 782 A.2d at 819.

The researcher-subject relationship is fundamentally different – it is not an arms-length transaction. This is so for at least two reasons. First, neither party acts solely in his own interests. The researcher acts in part to further his own career, to be certain, but he also acts to benefit society by advancing the state of knowledge. And the Common rule obliges him to consider his subjects' interests when he acts.[114] Subjects generally volunteer for research, at least in part, for unselfish reasons.[115] It is true that, in clinical research, the subjects often act at least in part because they hope for direct personal benefit. But most subjects are motivated at least somewhat by an altruistic desire to help advance societal interests.[116] And their involvement also directly helps advance the personal professional interests of the researcher. In short, neither researcher nor subject can be said to act wholly for himself.

Furthermore, there is an element of quid pro quo at work: because the subject helps the researcher, the former might have a legitimately heightened expectation that the researcher would at the very least, alert him to medically significant information in return. In some real sense, then, the relationship between researcher and subject is closer

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[114] It might even be argued that the researcher acts, in part, to benefit his subjects. True, the aim of research is not to directly benefit any particular subject – or even the class of subjects, generally – but to advance knowledge. But because research with human subjects is designed to advance knowledge about human health, it is intended, in an attenuated but nevertheless real sense, to benefit each subject. And to the extent that this argument has any teeth, it further suggests that the argument for a duty in the researcher-subject relationship is stronger.

[115] *See* Judith Daar, *Genetic Testing and Human Subjects Research*, 24 Whittier L. Rev. 454, 461-64 (2002). Some subjects are also paid for their participation in research, and for some this payment may well be the primary – if not sole – reason for participating. The analysis in this section arguably applies very differently, if at all, to subjects who are paid – at least for those who receive more than just token compensation or reimbursement for expenses. Whether any duty of disclosure ought to extend to subjects who participate primarily for financial compensation is beyond the scope of this paper. It should be noted, however, that notwithstanding the fact that the researcher-subject relationship is more akin to an arm's-length transaction when subjects are financially compensated, considerations including disparities in knowledge and other market failures persist.

[116] *See* Justin D. Rothmier, et al., *Factors Influencing Parental Consent in Pediatric Clinical Research*, 111 Pediatrics 1037, 1039-40 (2003) (discussing studies finding that altruism is a motivating factor for most people who enroll as research subjects).

to a cooperative or joint enterprise rather than an arms-length transaction. And although it might stretch credulity to suggest that the law of business partnerships should govern the researcher-subject relationship, it seems reasonable to assert that, because partnership law requires of each partner a duty to act on the other's behalf,[117] and because the relationship between researcher and subject is, on the spectrum between arm's-length relationships and partnerships, at the very least closer to partnerships than are the relationships in the third-party examination context, the argument for duty in the former context is stronger.

2. **Other Factors**

Other factors cited by the courts in support of imposing a duty in the context of third-party physical examinations also suggest that a similar duty should be imposed on researchers. For example, the burden on the researcher to disclose an individual research finding will often be minor, especially in comparison to the potential benefit to the subject – merely notifying the subject in writing would likely suffice. The provision of some data might be more burdensome – genetic data, for example, arguably should only be provided in tandem with genetic counseling.[118] And thus the burden might not be uniformly low. But even so, the burdens are likely to pale in comparison to the benefits – again, assuming a finding with a high degree of clinical utility, similar to those discussed in the third-party examination cases, and also assuming that the duty could be discharged by simply informing the subject of the finding and would not entail any subsequent obligation to treat or refer.

[117] *See*, *e.g.*, *Meinhard v. Salmon*, 249 N.Y. 548 (N.Y. 1928).
[118] *See* IRB Guidebook, *supra* note 18 ("Any disclosures of genetic information should be accompanied by appropriate counseling by trained genetic counselors.").

Like the doctors or insurance companies in the third-party physicals cases, researchers who discover individually significant research findings would be in a unique position to prevent harm. In fact, this consideration potentially weighs even more in favor of a duty to disclose in the research context, because a given individual research finding might be both completely unknown and unknowable by anyone outside the particular research team. For example, when genetic researchers make an initial discovery that a particular gene is linked with a higher incidence of a disease, they alone possess that knowledge, at least prior to sharing or publication. In such a circumstance, a subject with the relevant genotype could not possibly learn the salient information from any source other than the researcher. Once the discovery is published, of course, the information becomes widespread. But even then, an individual who wishes to learn if he in fact possesses such a gene might not be able to acquire that information elsewhere – in some circumstances, the test for the gene might be possessed exclusively by the researchers. Alternatively, a researcher might employ a test for a gene that is widely available but is prohibitively expensive.[119] This, too, increases the likelihood that the researcher alone will have either the knowledge of the genetic disorder or the ability to discover it. Thus, to the extent that the "unique position to prevent harm" foundation for a duty to disclose is taken seriously, it arguably weighs more heavily toward a duty on researchers than on third-party examiners because, at least in some circumstances,

[119] Consider, for example, that the tests for two genes that are linked with breast cancer, BRCA1 and BRCA2, are offered only by one company and can cost up to several thousand dollars each. *See* National Cancer Institute, *Fact Sheet: Genetic Testing for BRCA1 and BRCA2: It's Your Choice*, http://www.cancer.gov/cancertopics/factsheet/Risk/BRCA (last accessed May 15, 2008). If a research protocol sought to examine whether either BRCA1 or BRCA2 was linked with another type of cancer or a non-cancer disease, the researchers would necessarily learn the genotype of each subject with respect to the breast cancer gene or genes. The prohibitive cost of the test to the subjects, were they to obtain it outside the research context, increases the chances that the subjects will not learn of their genotype via other means.

researchers will, by virtue of their exclusive knowledge of the underlying scientific connection, *actually* be uniquely positioned to prevent harm.

3. **Variables in the Research Context**

The value of any particular individual research finding will vary widely, but that does not argue against the imposition of a duty, generally. For example, genetic researchers may learn that a subject has a genotype that predisposes him to only a slightly higher risk of developing a disease. Or a blood test may reveal slightly elevated levels of an enzyme that do not rise to the level of a clinical problem. In short, much of the individual information learned by researchers may have little or no clinical utility. But such variations in the clinical utility of individual information are not unique to research. Information learned during the course of third-party examinations will vary similarly. Thus, that much of the information learned during research will have limited clinical utility is not an argument against researcher duty per se but rather only an argument that such a duty will present in only limited circumstances. In any event, even extending a duty to less clinically useful information would likely be of little consequence, because absent clinical utility, the remaining elements of a negligence claim will likely not be met.[120]

What potentially matters more is that the nature of research relationships varies widely, and to the extent that the nature of the relationship shapes subjects' expectations, so too might the latter be expected to vary. At one extreme, we can imagine a subject whose involvement in a research protocol is limited to the donation of tissue for genotyping and the filling out of a questionnaire regarding his demographic information

[120] *See* discussion *infra* Part IV.

and perhaps his medical history. Such a scenario is likely commonplace among many types of population genetics studies.[121] Relationships in research can also be much more involved, however. Researchers may, for example, work closely with a particular family -- genotyping numerous family members, acquiring detailed personal information about each family member, and following up over time to learn more about the family members' medical developments. A researcher might also, of course, be a physician from whom his subjects receive care, perhaps over a long time period and for very serious medical conditions.

Ultimately, however, although the variation in research relationships should be considered, it probably should not be dispositive, because there are elements present in all researcher-subject relationships that alone arguably merit the imposition of a duty when information is discovered that bears on the health of the subject. For example, the relationship between researcher and subject is a professional one wherein consent is given for the researcher to have privileged access to private information, and, furthermore the researcher has received permission to impose upon his subjects at least in part for his own benefit.[122] Considered together with the fact that the researcher will likely be in a unique position to prevent harm and that burden of disclosure will often be relatively slight, especially as compared to the level of harm that could be avoided, this suggests that although the extent of the relationship between the researcher and subject should be a factor to consider, it should not be dispositive. And for these same reasons, neither should variations in the researcher's professional identity – whether she is a physician.

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[121] *See* Laura M. Beskow et al*., Informed Consent for Population-Based Research Involving Genetics*, 286 J. Am. Med. Ass'n 2315 (2001).

[122] *See* Miller, et al., *supra* note 56 (arguing that these factors give rise to a moral duty to disclose incidental research findings).

In fact, whether a researcher has a medical degree arguably ought not to matter in the analysis of duty. Notwithstanding *Pehle*, however, most courts that have imposed a duty on physicians in third-party physicals appear to have limited their holdings to physicians. Therefore, it might be asserted that the application to the research context should vary widely depending on whether the researcher was also a physician. But limiting the duty to physicians and basing it on their traditional role is especially problematic in the research context because it is illogical and it further muddies the already cloudy clinical research waters at a time when clarity is needed to promote the sorely needed public trust in the research enterprise.

There are several reasons why the professional status of the information holder – i.e. whether she is a medical doctor – might matter, but none convincingly demonstrate that the legal obligations regarding the disclosure of research findings should be different for non-physician researchers than for researchers who are also medical doctors. A physician's professional role qua physician is, of course, fundamentally different from the role of a researcher. A physician is a healer of individuals; a scientist is a generator of generalizable knowledge. But this overlooks that a physician is not acting in the role of a healer when she dons the researcher hat – in that case, she is a scientist, whose primary loyalty is to the protocol, just like non-physician researchers. Hence the argument that physician-researchers, and researchers generally, are not in a fiduciary relationship with their subjects.[123]

One reason that the professional identity of the researcher might matter is that a physician might plausibly be expected to have superior capacity to interpret the medical significance of certain research findings. This is undoubtedly true in many situations – a

[123] *See* Morreim, *supra* note 112.

physician has the professional training to diagnose, while the non-physician scientist generally lacks such ability. But in some circumstances, medical training may be neither necessary nor even helpful to the determination whether an individual finding merits disclosure. For example, when the research finding is not a medical diagnosis but rather a probabilistic assessment of risk, an M.D. is neither necessary nor sufficient for calculating the odds. And thus, when it comes to interpreting epidemiological data regarding possible linkages between a gene and a disease, for example, the investigator who is trained in interpreting such data should have a superior capacity for interpretation. Therefore, the superior capacity argument does not clearly cut either way; rather, it is context-dependent.

Research subjects might, however, have significantly different expectations about the provision of results based on whether the investigator is a physician or a scientist. This is particularly likely to be true when a subject is in a preexisting patient-physician relationship with the investigator. The question, though, is whether we should encourage or discourage such expectations. Therapeutic misconception, wherein research subjects – particularly those involved in clinical trials – falsely believe that the point of the research is to help them individually, is already both quite common and difficult to eradicate.[124] Because physicians and non-physicians are in the same professional role when they act in their capacities as researchers, encouraging differential expectations based on the professional identity of the researcher is unwise, in part because it threatens to further exacerbate therapeutic misconceptions, which in turn risks furthering public distrust of research and, ultimately, could lead to less participation in research. [125]

[124] *See* Appelbaum, *supra* note 108.
[125] *Id*.

Instead, the presence or absence of a legal duty to disclose individual research findings should turn on factors other than the professional identity of the investigator.[126] In essence, misguided expectations should not be the basis for duty. Although the therapeutic misconception is widespread, it is nevertheless erroneous. And basing a duty to disclose on misguided expectations of physician-researchers is just that – misguided.

In sum, the rationales put forth in the third-party physicals cases for imposing a duty resonate even more in the research context. But the particular reasoning of the physician-centered cases should not be imported into the researcher-subject relationship, in part because doing so would threaten to exacerbate the therapeutic misconception and subsequently further undermine already eroding public understanding of and trust in research. The minority opinions in *Petrosky* and *Nolan* and the majority opinion in *Pehle* provide a better approach for analyzing a duty to disclose in the research context, one that focuses on, among other things, the nature of the relationship rather than just the professional status of the examiner. The nature of the relationship between researcher and subject can vary a great deal, and those differences in research relationships should inform the duty inquiry, but they should not be dispositive, because even limited research relationships have sufficient qualities that they should arguably entail a duty to disclose.

IV. Other Elements of Negligence

The practical effect of a duty for researchers to disclose individual research findings would likely be somewhat limited, because establishing that researchers have a

[126] This argument is independent of the nature of the relationship between the subject and the researcher. Of course, a physician-researcher is often more likely to have a preexisting relationship with her subjects, and the nature of that relationship may well shape subjects' expectations and reasonably could serve as a basis for imposing liability. But that inquiry is fundamentally about nature of the relationship rather than the professional identity of the researcher.

duty to disclose individual research findings is only a first – albeit critical – step to establishing negligence-based liability for a failure to disclose. And just as the question of duty would present a new challenge for courts, so, too, would establishing the other elements of the negligence action – a breach of the duty that was the proximate cause of cognizable harm.

A. Scope of Duty

The first step in establishing a breach of a duty to disclose would be a determination of the scope of the duty. And this determination could be quite knotty. In medical malpractice cases, courts look to experts to establish the standard of care. Courts faced with a claim of researcher negligence might also look outside the courtroom for expert advice on the scope of the duty, and they therefore might look to the statements of various prominent organizations that have grappled with the question of when individual research findings should be revealed. But this field is still unsettled. A significant portion of research with human subjects is probably unlikely to generate individual research that would fall within the scope of a duty to disclose, even if such scope were broadly defined. But there are also many potential findings that might fall within the gray areas between those with clear medical significance, such as the discovery of a brain mass or a positive test for HIV, and those that are so preliminary that they lack even internal validity.

In the context of genetic information, where concerns based on the principle of nonmaleficence and stemming from potential harms from probabilistic genetic information, counter autonomy-based arguments for disclosure, several prominent

organizations have issued guidelines that seek to address the tension between the two principles by respecting both. Perhaps most prominently, The National Bioethics Advisory Commission (NBAC) put forth specific recommendations addressing whether and under what circumstances individual genetic results should be disclosed.[127] NBAC stated that IRBs should develop general guidelines for the disclosure of results, and that these guidelines should reflect that disclosure should only happen under the following circumstances:[128]

1. the findings are scientifically valid and confirmed,
2. the findings have significant implications for the subject's health concerns, and
3. a course of action to ameliorate or treat these concerns is readily available.

In essence, these three conditions describe results that have clinical utility -- some way to improve a subjects' health. If results have no clinical utility because they fail to meet any of the three criteria, NBAC considers the harm from disclosing such results to be greater than any good that might result. If, however, results have significant implications for health *and* there is something that can be done about the concerns, the equation favors the good that will result from disclosure over potential harms. Although there appears to be no empirical evidence available to gauge the extent to which the guidelines from NBAC are heeded, there is some anecdotal evidence suggesting that they are seen as authoritative, perhaps because they are one of the few sources of guidance that is directly relevant to this issue and because of the prominent stature of NBAC.[129] Because these

[127] *See* NBAC, *supra* note 17, at 71-72.
[128] *Id*. at 71
[129] *See*, *e.g*., Austin, *supra* note 12 (relying on NBAC guidelines in determining whether to reveal genetic information indicating a predisposition to Alzheimer's disease to subjects in a Japanese-American family

guidelines favor non-disclosure except in unusual circumstances, it could be argued that if those circumstances are met, disclosure should happen. However, these recommendations do not actually state that disclosure of results should or must happen under any circumstances; rather, they merely state that disclosure should not happen if any of the three of the criteria are not met.

Similar guidelines were issued late in 2004 by a working group from The National Heart, Blood, and Lung Institute (NHLBI), whose main objective was to "…discuss and make recommendations for reporting individual results from genetic tests to participants of Heart, Lung, Blood and Sleep research studies involving genetics."[130] Although the guidelines were thus only intended to apply directly to research under the auspices of NHBLI, the size and stature of this organization make these suggestions noteworthy nonetheless. The working group unanimously agreed on three key criteria that must be met before results can be reported to participants and their physicians and stated that if these criteria are met, results should generally not be withheld:[131]

1. The risk for the disease should be significant, i.e. relative risk >2.0. Variants with greater penetrance or associated with younger age of onset should receive priority
2. The disease should have important health implications, i.e. fatal or substantial morbidity or should have significant reproductive implications
3. Proven therapeutic or preventive interventions should be available

The working group also concluded that decisions about reporting results should *not* be made solely by the investigator and should be done only with IRB approval.

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study); Beskow et al., *supra* note 121 (a working group from the Centers for Disease Control used NBAC guidelines as the basis for its recommendations for designing informed consent documents regarding disclosure of results in genetic epidemiology research).

[130] NHLBI Working Group on Reporting Genetic Results in Research Studies Meeting Summary (2004), available at http://www.nhlbi.nih.gov/meetings/workshops/gene-results.htm (last accessed May 15, 2008).

[131] *Id*. at recommendation #3.

The NHLBI guidelines are thus very similar to those propagated by NBAC five years prior. Although NHLBI tries to provide a bit more advice about how a determination of 'important health implications' should be made, they still rely on vague terms like "substantial morbidity" and "significant reproductive implications." Thus, even if these recommendations are followed, there remains significant room for interpretation within the determination of whether specific results should be disclosed.

There is also at least one notable difference between NBAC and NHBLI. The latter organization's recommendations stated that if the three criteria are met, "…results generally should not be withheld."[132] This is a perhaps significant deviation from the NBAC guidelines, which, as noted earlier, did not include any language actually urging disclosure.

Perhaps in recognition of these outstanding unresolved issues, NHLBI made another relevant recommendation: "DHHS should issue formal, uniform guidance for IRBs, institutions, investigators and sponsors with respect to best practices for testing and reporting genetic results in human research studies."[133] Indeed, were DHHS to take this suggested step, it would not only eliminate much of the guesswork that researchers and IRBs must now face, it would also provide a much firmer basis to which a court could look if faced with the task of determining the scope of a duty to disclose in the research setting.

NBAC and NHLBI both set the bar for disclosure at (or near) clinical utility, but this recommendation is not without its critics. In particular, a working group from the Department of Health and Human Services (DHHS) offered a notable critique. This

[132] *Id*.
[133] *Id*. at recommendation #15.

group, which was convened specifically to study the recommendations in the 1999 NBAC report, issued its response in 2001. Included in that response were the following concerns about the second and third criteria for disclosure:[134]

> The Working Group is persuaded that individuals have differing personal perspectives about whether information has 'significant implications' for their own health . . . . Furthermore, even if there is no prevention or treatment measure that the researcher or IRB judges to be effective, having this information may allow the subject to make certain life choices or to engage in an intervention or additional research that the subject believes may be helpful.

Thus, the DHHS working group was clearly uncomfortable with the high bar for disclosure set by the NBAC report, and by the fact that the decision-making regarding disclosure would, were the NBAC guidelines to be followed, not take any personal preferences of the subjects into consideration. And the recommendations from NHLBI fall short of addressing these concerns. In fact, the criteria that most troubled DHHS (the second and third criteria for disclosure in the NBAC report) are essentially the same as criteria #2 and #3 in the NHLBI report. The DHHS working group recommended convening yet another working group to address these concerns, but a review of relevant sources gives no indication that this has yet come to pass.

Alzheimer's disease (AD) offers an illuminating example of these competing considerations. At least one research team utilized the NBAC guidelines in deciding not to disclose to its subjects genetic information regarding an increased risk for AD, concluding that because the disease was not preventable or treatable, such information would have no clinical utility, and thus the harms from learning such information, such as increased anxiety, outweighed the minimal benefits.[135] But recent data suggests that the

[134] DHHS Response, *supra* note 34, at 24.
[135] *See* Austin, *supra* note 12.

harms from such disclosures might be overstated and the benefits understated.[136] And at-home kits that test for a genetic predisposition to Alzheimer's disease are now commercially available, indicating that there may be a demand for genetic information lacking in clinical utility – i.e. that at least some people want to know if they are genetically predisposed to a disease, even when there are no proven preventative steps that can be taken. All of this undermines the argument that only information deemed clinically useful is more helpful than harmful. And it may ultimately convince organizations like NBAC or NHLBI to reassess their assertions that clinical utility is the proper threshold for reporting. It seems unlikely, however, that it will ultimately affect the legal determination of the scope of a duty to disclose – at least not unless tort law changes to encompass broader notions of harm.

Thus, in spite of its deficiencies, the bar of clinical utility is at least legally defensible and is a plausible parameter for the scope of a duty to disclose. If an individual research finding lacked clinical utility, it would be difficult for an individual to demonstrate that a tangible harm resulted from not being informed of such finding, and if the failure to disclose was not the proximate cause of tangible harm, a critical element of negligence would be missing. Thus, NBAC and NHLBI have provided guidelines that, if followed, would seem to protect a researcher from liability *if* the determination of clinical utility is proper.

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[136] *See* Winston W. Chung, et al., *A New Scale Measuring Psychological Impact of Genetic Susceptibility Testing for Alzheimer's Disease,* Alzheimer Disease and Associated Disorders (forthcoming 2008) (discussing studies that revealed that risk status for AD could be disclosed safely); Serena Chao, et al., *Health Behavior Changes after Genetic Risk Assessment for Alzheimer's Disease: The REVEAL Study*, 22 Alzheimer Disease and Associated Disorders 94 (2008) (study found that people who learn they are at higher risk for AD are motivated to engage in healthy behaviors, even though the benefits of such behaviors on their risk for AD are uncertain).

A vexing problem, remains, however: the determination whether a particular individual research finding has clinical utility may often be far from simple, and the likelihood that such determinations would be made by the researchers, either alone or in consultation with an IRB, further complicates the issue because researchers' incentives regarding disclosure are arguably not well aligned with the interests of their subjects. The researchers may have conflicting interests that might favor a lower threshold (perhaps to increase the perception of importance of the study) or a higher one (to avoid the expense and inconvenience of disclosure). In addition, the investigators may not be adequately trained to assess clinical utility. IRBs may also not be in a position to properly evaluate clinical utility because the members may lack the necessary expertise. IRB members are charged with protecting human subjects in research, not with making statistical or medical determinations of clinical usefulness, and because they are selected specifically for the former task, the latter may be beyond the scope of both their specialties and their mandate. An additional issue is whether IRBs, which have been widely characterized as being overburdened,[137] would even have time to monitor the study and assess the results. Thus, a case can be made that the critical determination of whether a given result will have clinical utility for a subject should be not be made by the researchers or the IRB at all. In fact, the DHHS working group's response to NBAC's guidelines expressed concern about this particular point: "[The Working Group] . . . questions whether an IRB or investigator is necessarily qualified to make such judgments on behalf of the subject."[138]

[137] *See, e.g.*, David Resnik, *Liability for Institutional Review Boards: From Regulation to Litigation*, 25 J. Legal Med. 131 (2004).
[138] DHHS Response, *supra* note 34, at 24.

In any event, the determination of the scope of any duty to disclose might plausibly be influenced by the guidelines from NBAC and NHLBI. These guidelines, however, lack answers to important questions, such as how the determination of clinical utility should be made. Both sets of guidelines also fail to account for the other issues raised by the DHHS working group – that, regardless of whether there is a proper determination as to whether the results constitute significant health information, the individuals who are taking part in the research may have very different ideas about what information they consider important to their own health. In fact, conceptions of important health information will vary not only between researchers and subject but also among subjects themselves. When the decision whether to return results is made by the investigator, the IRB, or both, but without individual consultation with each subject, it will necessarily be incapable of taking all of these differences into account. And when a research subject is not provided information that he or she feels has important health implications, dissatisfaction and the potential for litigation can result.

B. Proximate Causation

The most likely route to establish that the failure to disclose was the proximate cause of harm would likely be a claim that the lack of information resulted in the 'loss of a chance'[139] to act to prevent the formation of the disease, the progression of the condition, or to change medications, depending on the circumstances of the particular case. For certain results, this would be rather straightforward – failure to notify of evidence of an early-stage disease that would have been preventable or treatable at the time the result was obtained, for example, would appear to fit neatly within the loss-of-a-

[139] Furrow et al., *supra* note 25, at 300.

chance framework. But for many individual research findings, the causation picture will be much fuzzier. And for genetic results in particular, proximate causation could prove quite challenging: the multi-factorial nature of most common genetic diseases – most arise from a combination of multiple genetic and environmental sources – would complicate any determination of causation. Thus there are likely to be, in most cases, numerous factors that contribute to the presence of a disease or condition in any one individual. And it therefore may often be quite challenging to prove that a failure to notify an individual of her genetic susceptibility was the proximate cause of a disease.[140] In cases involving harm alleged to have been suffered as a result of an interaction between a medication and a genotype, it may be somewhat easier to prove proximate causation. However, some of the same hurdles remain, including the fact that a research result will, if anything, probably only indicate a susceptibility to, rather than a certainty of, harm from a medication.

If the question of compensable harm was reached by the court, it, too, might prove challenging, because the multi-factorial nature of most common diseases would likewise complicate this inquiry, and a court would be faced with determining how much of a 'loss of a chance' the plaintiff suffered. To do so, a court might have to make the difficult determination, for example, of how much a susceptible genotype contributed to the development of the disease or reaction to medication. And courts may well defer, thinking themselves ill-suited for such calculations.

[140] This is akin to the difficulties of proving causation in the field of toxic torts, where similar problems of multiple potential causative factors arise.

The point here is that, even in the event that a duty to disclose is imposed on researchers by courts, the other elements of a negligence action still pose potentially substantial barriers to an ultimate finding of liability.

V. **Potential Implications of a Researcher Duty to Disclose**

If a court holds – or even hints – that researchers have a duty to disclose individual research findings to their subjects, investigators might well react to limit their legal exposure. At least two plausible steps can be expected – changes to informed consent documents and more anonymization of tissue samples. Each of these is problematic, however, and the contractual approach, in particular, may do less to reduce exposure than might be hoped. Because of the potential for a patchwork of different laws regarding disclosure in different states, a uniform regulatory approach may be preferable.

A. Contract

One plausible approach to the threat of liability is to attempt to contract around the duty to disclose. In practice, this could be accomplished by inserting language into the informed consent document stipulating that individual research findings will not be returned to subjects. In theory, this would both absolve researchers of any such duty and honor the wishes of both parties – after all, if a subject objects to such a term in the informed consent document, he can either negotiate a change or opt not to participate. And because informed consent documents have previously been treated as binding

contracts by courts,[141] there is reason to suspect that such an approach would be honored by the courts and would thereby be effective at limiting researcher liability.

There are several problems with the contractual approach, however. To begin with, the informed consent process would likely need to be changed considerably both to create consistently enforceable contracts and to satisfy ethical concerns. The inadequacies of informed consent are legion and have been well-documented and discussed.[142] Among other things, subjects often fail to understand the content of consent forms,[143] and rather than being treated as a process by which the researcher ensures meaningful informed consent, many investigators appear to treat informed consent as merely a goal: to get the subject's signature on a document.[144] In short, researchers have generally fallen far short of the recommendations made by, among others, the Office for Human Research Protections that informed consent should be thought of as a process of educating potential subjects rather than as merely as a single step motivated by a desire to quickly obtain a signature on a form.[145]

Furthermore, many investigators currently engaged in research with human subjects omit discussions of whether and how individual information might be communicated.[146] And many of those who do address the matter do so merely cursorily, noting quickly that individual results will not be disclosed without providing

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[141] *See* Michelle M. Mello & Steven Joffe, *Compact versus Contract – Industry Sponsors' Obligations to Their Research Subjects*, 356 New Eng. J. Med. 2737, 2741 (2007); *Grimes*, 782 A.2d at 843-844 (holding that an informed consent document can create a binding contract).
[142] *See*, *e.g.*, Carl H. Coleman, *Duties to Subjects in Clinical Research*, 58 Vand. L. Rev. 387, 414 (2005) (collecting sources).
[143] *See* James Flory & Ezekiel Emanuel, *Interventions to Improve Research Participants' Understanding in Informed Consent for Research: A Systematic Review*, 292 J. Am. Med. Ass'n 1593 (2004)
[144] *Id*.
[145] *See* IRB guidebook, *supra* note 18.
[146] Matthew Gordon, *Disclosure of Individual Genetic Results to Research Subjects: A Pilot Review of Current Practices* (June, 2005) (unpublished M.P.H. thesis) (on file with author).

justification.[147] And this is despite recommendations from several sources that the consent document should address whether individual results will be disclosed and justify that decision and the provision of model language to that effect created for consent forms.[148] Regrettably, many investigators appear to have ignored such suggestions. An additional problem is that consent forms that do suggest the possibility of individual notification often use vague language about the circumstances under which disclosure might occur.[149] And vague language has the potential to create more legal problems.

Therefore, merely recommending that consent forms deal with this issue more explicitly and forthrightly might well have limited effect. Of course, this is not an argument against a contractual approach per se, but rather an observation about potential practical limits of such an approach. Certainly, if researchers are sued for failure to disclose results – and especially if any such litigation is successful– researchers may well begin to address individual findings much more frequently, thoroughly, and precisely in consent forms. But there are other potential problems with the contractual approach that reach deeper and are less easily resolved.

First, courts might not consistently uphold provisions in informed consent documents purporting to eliminate the obligation to disclose medically significant research findings. At least three considerations seem relevant here. First, as discussed previously, the Common Rule prohibits exculpatory language in the informed consent inform.[150] If a court construes the disclosure of research findings as a researcher's duty or a subject's right, it might invalidate any provisions in the consent form that would

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[147] *Id*.
[148] *E.g*., Beskow et al., *supra* note 121(providing a template informed consent form for population-based genetics research).
[149] Gordon, *supra* note 146.
[150] 45 C.F.R. § 16.116(b)(5).

purport to circumvent that duty or negate that right.[151] Second, aside from the Common Rule, a court might find any such contractual provision invalid purely on public policy grounds. Indeed, in *Reed*, the court said that it would not allow physicians to contract around the duty to disclose in the context of third-party physical examinations because doing so would violate public policy.[152] Third, in certain situations, courts might take a dim view of the voluntariness of the consent. In particular, when physicians recommend participation in a clinical trial to their (perhaps desperately) ill patients, the subsequent decision of those patients to participate is arguably not wholly voluntary.[153]

The point is not that courts necessarily will regularly choose to invalidate or disregard provisions in informed consent forms that purport to relieve an investigator of the duty to disclose individual research findings with medical significance to her subjects. It is merely that there are plausible reasons why some courts might choose to do so. And a patchwork of different court holdings on this issue would seem problematic for researchers, especially for those studies that involve institutions in multiple states. Consistency would seem to be far preferable for researchers.

Furthermore, to the extent that the contracting approach draws support from a market justification, it is problematic because it assumes a faith in the marketplace that seems misplaced here. In theory, the disclosure of individual research findings could be left to the market, with the notion that potential research subjects might shop among different protocols, selecting the one with the package of risks and benefits that best suits

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[151] *See Vodopest,* 120 Wash.2d 840 (invalidating exculpatory clause in consent form).
[152] *Reed*, 166 N.J. at 106-07.
[153] *See* David A. Lenrow, *The Treating Physician as Researcher: Is Assuming this Dual Role a Violation of the Nuremberg Code?*, 25 Temp. J. Sci. Tech. & Envtl. L. 15, 40-41 (2006) (arguing that informed consent might not truly be the product of free choice when a treating physician suggests to a patient that the latter enroll in a clinical trial).

their preferences. If such a market worked and subjects preferred protocols with contract terms that promised them that they would be notified of any individually important information, such a preference would presumably come to be represented in the marketplace and increasing numbers of researchers would promise to return individual research findings.

But there is reason to doubt that such a well-functioning market is likely either to exist now or to develop in the future in the context of research with human subjects. A searching analysis of a market for research is well beyond the scope of this paper, but it is worth noting that several market failures seem likely. First, the information asymmetry between researchers and potential subjects is vast and likely unbridgeable without substantial effort.[154] And due in part to their lack of information and understanding, subjects might reasonably be expected to consistently undervalue the provision of research findings. Second, there are likely to be far too few sellers (researchers) in many market segments. For example, many rare diseases or traits are likely to have few, if any, ongoing investigations. Thus, an individual with such a trait who wishes to benefit both society and kin by enrolling in a research protocol may have vanishingly few – if any – options.[155] In response, it might be argued that such an individual can just choose to forego participation in research altogether. But this ignores that, in certain situations, a

[154] Consider, in this light, the difficulty overcoming just one misperception that subjects have about research – the therapeutic misconception. *See* Appelbaum, *supra* note 108 (detailing how the therapeutic misconception can persist even after extensive explanations to subjects).

[155] Of course, such an individual might also have more leverage than the typical potential research subject by virtue of the trait's rarity and his willingness to participate. And such leverage might conceivably be used to adapt the research protocol – or at least the section of the protocol dealing with the return of individual results – to his liking. But that presumes that bargaining over terms in the consent document will actually occur, and that seems unlikely. Also, that the rare individual might have more leverage in a hypothetical negotiation with a researcher does not indicate the presence of a well-functioning marketplace.

clinical trial might be the only realistic option for an individual to receive treatment.[156] Therefore, the decision whether to become a research subject is not always a wholly free choice. Third, the notion that any bargaining between researchers and prospective subjects over terms in the informed consent document will actually occur seems far-fetched. Rather, it can be expected that researchers will present the informed consent document in a take-it-or-leave-it fashion, in part because in some situations, they might not be able to adapt a study to meet individual preferences regarding disclosure of research findings.

Finally, even assuming that investigators did modify their consent forms to treat the issue of disclosure of individual research findings more directly and in more depth and that courts consistently treated those forms as contracts that defeated challenges based on a failure to disclose, the normative question remains. Contracting around a duty to disclose *might* resolve the legal issue in favor of researchers and against disclosure. But is this optimal? A world in which research subjects were routinely provided with individualized information gleaned from their participation might well be a better world. Certainly, it would be one in which more people possessed more personal medical information that was at least potentially useful. It might also be one, however, in which the cost of research is higher and less research occurs. It is not entirely clear what the normatively desirable outcome is, but it is very plausible that we cannot trust that the desired outcome will result from widespread contracting out of duties to disclose. If the contract approach was likely to actually reflect the consensus view of researchers and

[156] *See* Nancy M. P. King, *Defining and Describing Benefit Appropriately in Clinical Trials*, 28 J.L. Med. & Ethics 332, 339 (2000).

subjects rather than just resulting from an imposition of researchers' desires to avoid liability, the outcome might be more worthy of respect. But that seems unlikely.

Widespread and routine non-disclosure might also harm the research enterprise in the long run. As discussed previously, public distrust of research has been growing, and many clinical trials struggle to find sufficient numbers of subjects.[157] To the extent that the difficulty finding subjects is linked to the growing distrust of clinical trials – which seems highly plausible – research participation may decline more if, for example, reports surface of subjects suffering otherwise preventable harm because a researcher failed to disclose potentially life-saving, or at least very helpful, individual information. In short, because the recruitment of subjects for research depends at least in part on potential subjects both valuing and trusting researchers, steps that might undermine either should not be taken lightly. And thus, even if routine nondisclosure appears to benefit researchers in the short term by saving costs and reducing other burdens, the ultimate result of a system in which researchers either have no tort liability to disclose individual research findings to their subjects or routinely contract around such liability may be a net negative for the enterprise of human subjects research.

B. Anonymity

Researchers might also respond to the threat of an imposition of a duty to disclose by changing research protocols to foreclose the possibility of disclosure. This can be accomplished by de-linking tissues donated for research from any identifying information. Completely anonymizing tissue samples in this way would mean that no

[157] *See*, *e.g.*, Anthes and Allen, *supra* note 7.

research finding could be traced back to a particular donor, and thus disclosure would not be an option.

The anonymization approach has both practical and ethical limits, however. From a pragmatic perspective, not all research can be effectively anonymized. In general, research that involves more extensive interaction with subjects often requires that the identity of the subjects remain known. For example, consider brain imaging studies wherein a subject's brain is actively imaged as he remains under the supervision of the research team. Any result obtained during the active imaging is, of course, immediately linked with the person in the room. Family genetic studies also are not readily anonymized. Clinical trials, although double-blinded, are generally incapable of complete anonymization. But many types of research – in particular, many studies in which subjects merely contribute tissue samples – are amenable to anonymization. And although anonymization can limit the usefulness of tissue samples and thus potentially has drawbacks for the researcher, the threat of liability may well encourage increased de-linking of identifying information from tissue samples. While taking such action would insulate researchers, it is also ethically problematic, at least in certain contexts.[158] But to the extent that the fear of liability trumps the ethical and practical considerations and researchers anonymize at higher rates as a result, the imposition of a duty on researchers to disclose medically important individual research findings may accomplish very little, at least in certain areas of research, beyond decreasing the usefulness of research data.

[158] *See* American Society for Human Genetics, *Statement on Informed Consent for Genetic Research*, 59 Am. J. Hum. Genet. 471(1996) ("Although there are benefits to anonymization, investigators are cautioned about the appropriateness of anonymizing data, especially when there is medical intervention available for the disorder being studied.").

C. Regulatory change

A change in the Common Rule or the issuance of formal, uniform guidelines from DHHS appears to be a superior alternative to the imposition of duty by common law and the expected reactions by researchers. Change originating at the federal regulatory level offers several advantages. First, researchers will likely benefit from uniform regulations instead of interstate variation, especially when they are engaged in multi-center research conducted across multiple sites in multiple states. Predictability and stability are also particularly valuable for long-term research projects. It is therefore not surprising that researchers have already called for uniform guidelines that are harmonized across all federal agencies.[159]

A change in the Common Rule or the issuance of guidelines from DHHS is also advantageous in that it would presumably arise from a more inclusive process, with researchers and the public each given a chance to weigh in on the topic. While such opportunities are not wholly foreclosed in litigation – interested organizations could have their voices heard via *amicus curae* briefs, for example – the likelihood of an inclusive process is higher seems change comes via federal agencies rather than the judiciary, for the following reason. Although it might be the case that widespread changes in research would only result from multiple court decisions that presumably reflected a growing consensus resulting from inclusive deliberation, the notion that widespread change will only be triggered by widespread court decisions may be misguided, and thus widespread and inclusive deliberation is likely to be absent. Because many research projects are

[159] *See* NHLBI, *supra* note 130, at recommendations 13 and 15 ("13. Recommendations regarding reporting of genetic results arising from this NHLBI working group should be coordinated and harmonized across all DHHS agencies (NIH, FDA, CDC, HRSA, etc.) and other federal agencies funding such research if possible. . . . 15. DHHS should issue formal, uniform guidance for IRBs, institutions, investigators and sponsors with respect to best practices for testing and reporting genetic results in human research studies.").

coordinated across multiple sites in different states, researchers could well be extra cautious. And thus a ruling in only one state court might trigger changes far beyond its borders.

Finally, regulatory change offers the advantage of decision-making by experts in the field instead of lay judges. Human subjects research and the potential provision of individual research findings can be complex and intricate topics. Although the judiciary has grappled with them before, on occasion, it is at least plausible that because decisions about duties in research have potentially broad implications for the research enterprise, they are better made by parties with intimate knowledge of the field.

D. Limits

Extending a duty to disclose to researchers arguably moves the law too far in the direction of a general duty to rescue. But those who fear a move toward a general duty to rescue should not be particularly threatened by a duty on researchers, because the rationale for the duty is based in large part on the pre-existing professional relationship and the duties already inherent in it. Thus, the reasoning presented here does not extend to imposing liability on purveyors of at-home genetic tests, even though those purveyors will gain access to privileged information and potentially be in a unique position to prevent harm, because interactions with such purveyors are arm's-length transactions, and they are not based on pre-existing relationships with duties already attached.

VI. Conclusion

Research with human subjects advances many important societal goals. And courts appear appropriately wary of introducing new legal constraints into the research enterprise. But the common law has advanced such that the imposition of a researcher duty to disclose individual research findings that are clinically useful to subjects appears to be a logical next step. In fact, the case for a researcher duty to disclose is arguably significantly stronger than for duties already imposed by the common law. Because a common law duty and the expected reactions to it are potentially problematic for the research enterprise, a uniform federal regulatory approach offers significant advantages.